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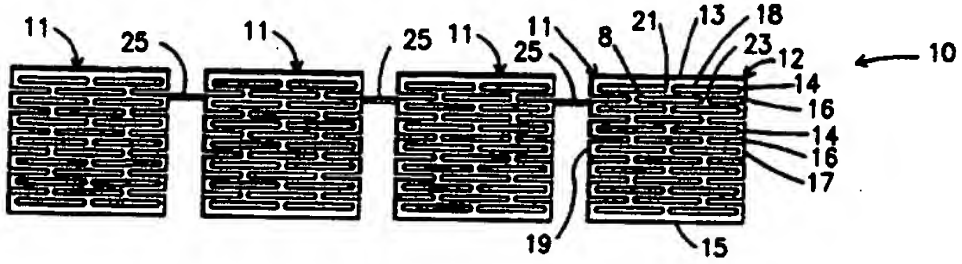

(57) Abstract

Interconnected stents, coated microporous stents and method of coating are disclosed. The inventive stent (10) consists of a tubular member (11) interconnected to another tubular member (11) with a flexible member (25), each stent made from a flat sheet assembled together through a technique such as surface fusing. Preferably, the stent is made up of a plurality of spaced rows of slots with spaces between adjacent slots within a row staggered with respect to corresponding spaces on adjacent rows. In a first embodiment of a coated stent, a coating is attached to the stent only at a single area of line contact (130) on the outer surface of the stent with the remainder of the coating being larger than the unexpanded stent, but being made of dimensions designed to snugly receive the outer surfaces of the stent when it is expanded within a blood vessel.

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MULTIPLE INTERCONNECTED STENTS AND METHOD OF COATING STENTS

BACKGROUND OF THE INVENTION

The present invention relates to multiple interconnected stents, a covered microporous stent and method of coating. Coated stents are known as stents that are designed to expand at the site within a blood vessel where they are intended to engage the internal wall of the blood vessel to reinforce it.

In using stents it is often the case that the area where repair and/or reinforcement is required extends around one or more curves in a tortious path. Under such circumstances, a single stent will not adequately perform the job of strengthening and reinforcing the blood vessel. Since the individual stent must be made of a rigid construction to perform its reinforcing task, where a tortious path of a blood vessel must be strengthened and/or reinforced, a plurality of stents must be interconnected together to cover the entire length of the area where reinforcement is necessary.

The following prior art is known to Applicant:

United States Patent 4,733,665 to Palmaz
United States Patent 4,739,762 to Palmaz
United States Patent 4,776,337 to Palmaz
United States Patent 5,102,417 to Palmaz
United States Patent 5,195,984 to Schatz
United States Patent 5,383,892 to Cordon et al.
United States Patent 5,421,955 to Lau et al.
United States Patent 5,443,496 to Schwartz et al.
United States Patent 5,443,498 to Fontaine
United States Patent 5,449,373 to Pinchasik et al.

Of the above-listed references, United States Patent 5,102,417 to Palmaz, and the patents to Schatz, Cordon et al., Lau et al.,

Schwartz et al. and Pinchasik et al. are most noteworthy as teaching interconnection of a plurality of stents together. However, none of these references teaches the combination of a stent formed from a single fabrication method having the configuration disclosed herein along with the manner of interconnection of multiple stents disclosed herein.

Currently available stents are known to cause restenosis. Restenosis can be caused by incompatibility of the metallic surface of the stent that engages the inner walls of the blood vessel giving rise to subacute thrombosis, usually within four weeks of implantation of the stent. Another possible cause of restenosis is the recoil of the metallic surface of the stent when placed along the internal wall of the artery. Such recoil does not occur immediately, but, rather, when the stent pulses due to its elastic nature, stresses act downwardly toward the stent resulting in gradual diminishing of the luminal diameter.

Additionally, most commercially available stents have an open mesh area when they are expanded and rapid ingrowth of collagen cells and smooth muscle cells gradually occurs through these open areas. Collagen cells contributing toward intimal hyperplasia eventually result in the narrowing of the lumen diameter. Additionally, sometimes, at the location where the stent is to be placed, such as, for example, in saphenous vein grafts, thrombus exists that must be bypassed. Finally, in the aorta and peripheral arteries, a large portion of the aneurysmal sac may have to be bypassed prior to stent implantation.

Use of polymeric or biologic material to coat a stent is generally known. However, in such coated stents, when they are expanded within a blood vessel, the coefficient of expansion of the coating greatly differs from that of the expanding stent such that, upon expansion, the surface of the coating tears rendering the expanded stent uncoated. If, as a solution, the coating is applied more thickly, such a thick coating can deter stent expansion or can have such a high profile that implantation into the body is difficult. The same problem occurs when a stent is coated by sandwiching it between inner and outer coating layers. If the stent cannot be expanded to its full intended diameter, the success of the implantation can be drastically compromised.

While the prior art does describe the concept of providing a stent with a coating, Applicant is unaware of any prior art that specifically describes whether such a coating surrounds the individual members of the metallic stent or whether such a coating covers all of the gaps between the various interstices of the expanded stent.

The prior art also describes biologic coatings such as collagen gelatin to be employed on a balloon expandable or thermally expandable stent. To coat such a stent, it is placed in a mandrel and then dipped into the biologic solution and then dried in an oven. Applicant is unaware of the nature of the resulting properties of the stent when expanded.

Applicant is also aware that stents have been coated with a polymeric material such as silicone that renders the resulting

stent impervious to any incursion of biologic tissue. However, in such stents, the impervious nature of the coating deters the healing of the surrounding tissues.

The following prior art is known to Applicant:

United States Patent 5,234,457 to Andersen
United States Patent 5,330,500 to Song
United States Patent 5,344,426 to Lau et al.
United States Patent 5,443,499 to Schmitt.

None of these patents teaches the features and aspects of the present invention as set forth hereinbelow, including the particular stent coatings nor the method of so coating a stent.

SUMMARY OF THE INVENTION

The present invention relates to embodiments of multiple interconnected stents. In each of the embodiments of the present invention a plurality or multiplicity of stents are interconnected together by interconnection means to form an elongated multiple stent configuration. In each embodiment, each stent is made from a rectangular piece of material formed in a roll with the facing edges fused together by means such as plasma energy fusing, LASER, ultrasound, or any other suitable means. Each stent so formed includes a configuration consisting of multiple rows of slots spaced by spaces with each space being staggered with respect to spaces of adjacent rows.

Each separate embodiment differs from the other embodiments as providing its own means of interconnection of adjacent stents. Thus, in a first embodiment, adjacent stents are interconnected by a single flexible resilient bar. In a second embodiment, adjacent stents are interconnected by means of U-shaped members fused

together. In a third embodiment, adjacent stents are interconnected by an integral piece of material having slots extending orthogonal to the slots in the adjacent stents.

In a fourth embodiment, similar to the first-mentioned embodiment, adjacent stents are interconnected by means of flexible resilient bars. However, different pairs of interconnected stents have bars vertically staggered with respect to other pairs of interconnected stents. In a fifth embodiment, adjacent stents are interconnected by virtue of a plurality of vertically spaced connectors resembling the letter "H".

In a sixth embodiment, adjacent stents are interconnected by a multiplicity of vertically spaced elongated flexible resilient bars. In a seventh embodiment, adjacent stents are interconnected by virtue of a multiplicity of flexible resilient members resembling the letter "W".

In all of the embodiments of the present invention, the stents as interconnected together may be expanded within a blood vessel through the use of means such as, for example, a balloon catheter or a mechanical spreader.

The present invention also relates to a polymer or biological material coated microporous stent and method of coating. The present invention includes the following additional interrelated objects, aspects and features:

In a first embodiment of a coated stent, a coating is attached to the stent only at a single area of line contact on the outer surface of the stent with the remainder of the coating being

larger than the unexpanded stent, but being made of dimensions designed to snugly receive the outer surfaces of the stent when it is expanded within a blood vessel.

In the method of making the above-described coating, the unexpanded stent is placed over a mandrel and is then inserted within an elongated recess eccentrically located within a larger mandrel with the recess having an elongated opening on a peripheral edge thereof. When the stent so assembled to the mandrels is covered with the coating, the coating surrounds the outer mandrel and connects with the stent only at the area of the peripheral linear opening. When the mandrels are removed, what remains is the stent having an enlarged coating attached thereto only at one linear elongated location. This embodiment is practiced concerning a stent that is intended to be expanded through the use of expansion means such as, for example, a balloon catheter or a mechanical expanding tool.

The present invention also contemplates coating of a stent of the type known as a "self-expanding" stent that is programmed to self-expand at a particular temperature by either using the shape memory properties of the metal or by using the flexibility and elasticity of the metal. In this embodiment, prior to programming the formed stent, the stent is placed in a container of coating material and is coated. Thereafter, the stent is programmed in the desired manner and is subsequently physically compressed and kept inside a sheath. The stent is placed within the blood vessel still within the sheath, and the sheath is then removed, allowing the

stent to expand to its desired configuration.

The present invention is intended to fulfill the following objects, aspects and features:

(1) To develop an ultrathin thin coating on a stent that is so configured that, when the stent is expanded, the outer expanded diameter of the stent is equal to the inner wall diameter of the coating with the structure of the coating being uncompromised.

(2) The coating so developed has the property of microporosity that facilitates controlled ingrowth of tissue within the coating to provide a neoinitimal healing mechanism.

(3) The coating may be provided with specific substances that are designed to enhance the healing properties of the stent.

(4) The wall thickness of the coating is intended to be extremely thin, on the order of 5 to 80 mils in thickness. For larger diameters the thickness of the coating can be up to 100 mils thick.

(5) The coating provides a conduit for dilatation of the plaque, can bypass a thrombus or eliminate an aneurysmal sac.

Where a plurality of stents are attached together in a manner to be described in greater detail hereinafter the length of the coating and the stent may be varied so that the stent runs some or all of the entire length of the microporous coating. Additionally, if desired, the stent may be intermittently placed within the coating or may be placed at only the proximal and distal ends thereof.

These and other objects, aspects and features of the present

invention will be better understood from the following detailed description of the preferred embodiments when read in conjunction with the appended drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a top view of a first embodiment of the present invention before the rectangular pieces are rolled and fused to form the multiple stents.

Figure 2 shows a side view of the embodiment of Figure 1 after the stents have been formed.

Figure 3 shows an enlarged side view similar to that of Figure 2.

Figure 4 shows a side view of a second embodiment of the present invention.

Figure 5 shows a side view of a third embodiment of the present invention.

Figure 6 shows a side view of a fourth embodiment of the present invention.

Figure 7 shows a side view of a fifth embodiment of the present invention.

Figure 8 shows a side view of a sixth embodiment of the present invention.

Figure 9 shows a side view of a seventh embodiment of the present invention.

Figure 10 shows a side view, partially in cross-section, of a multiple stent in accordance with the teachings of the present invention as it is being inserted within a blood vessel.

Figure 11 shows a further side view of a stent attached over an insertion mechanism.

Figure 12 shows a cross-sectional view along the line 12-12 of Figure 11.

Figure 13 shows a view similar to that of Figure 12 but with the stent expanded.

Figure 14 shows a view similar to Figure 12 of a different stent configuration.

Figure 15 shows a view similar to that of Figure 13 with the stent of Figure 14 expanded.

Figures 16 and 17 show an expanding mechanism in the expanded and closed configurations, respectively.

Figure 18 shows further details of the mechanical expanding mechanism shown in Figures 16 and 17.

Figure 19 shows a top view of a flat piece of material intended to be formed into a single stent.

Figure 20 shows a perspective view of the material shown in Figure 1 formed into a single stent.

Figure 21 shows an exploded perspective view of the stent shown in Figure 20 with relation to a solid plastic mandrel over which it is to be placed.

Figure 22 shows the stent placed over the mandrel of Figure 21.

Figures 23 and 24 show the process of placing the stent and mandrel of Figure 22 within a recess of a larger mandrel.

Figure 25 shows a cross-sectional view along the line 25-25 of

Figure 24 after the coating process has taken place.

Figure 26 shows the process of removing the coated stent from the larger mandrel.

Figure 27 shows a cross-sectional view along the line 27-27 of Figure 26.

Figures 28 and 29 show top views of two additional different embodiments of stents made up of a plurality of stent sections interconnected together.

Figure 30 shows a side view of the configuration of the stent and mandrels shown in Figure 24.

Figure 31 shows a side view of an alternative process wherein two stents are coated on a single mandrel.

Figure 32 shows a side view of the practicing of a further process wherein three spaced stents are coated on a single mandrel.

Figure 33 shows the process of inserting a balloon catheter within the coated stent.

Figure 34 shows the balloon catheter within the stent with the outer coating wrapped closely therearound for insertion.

Figures 35 and 36 show an exploded perspective view and a perspective view, respectively, of the process for attaching a stent over a mandrel in a further process in accordance with the teachings of the present invention.

Figure 37 shows a plurality of mandrels and stents corresponding to Figures 35 and 36 and suspended within a bath of coating material within a tank.

Figure 38 shows the stents of Figure 37, after coating, and

placed within an oven to dry the coating material.

Figure 39 shows a side view of a stent coated in accordance with the teachings of the process illustrated in Figures 35-38.

Figures 40-42 show the sequential process for inserting the stent, coated in accordance with the process illustrated in Figures 35-38 within a blood vessel.

SPECIFIC DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference, first, to Figures 1-3, a first embodiment of the present invention is generally designated by the reference numeral 10. Figure 1 shows the first embodiment 10 prior to forming of the stents from generally rectangular pieces 11 shown in the figure. In all of the embodiments of the present invention, each stent is formed from a rectangular piece such as the rectangular piece 11. As such, for ease of understanding, in each of the embodiments, these rectangular pieces will be referred to using the reference numeral 11.

As should be understood from Figure 1, each rectangular piece 11 has a top edge 13 and a bottom edge 15 as well as side edges 17 and 19. Each rectangular piece 11 has a body 12 that includes a multiplicity of rows 14, 16 of slots 18, 8, respectively, with the slots 18 being separated by spaces 21 and with the slots 8 being separated by spaces 23. As should be understood from Figure 1, the spaces 21, 23 are staggered with respect to one another in adjacent rows 14, 16. This configuration of slots and spaces is employed in each of the embodiments of the present invention. In the embodiment illustrated in Figures 1-3, adjacent pieces 11 forming

stents are interconnected by virtue of flexible resilient bars 25. As seen in Figure 1, in particular, the bars 25 are co-linear.

The rectangular piece 11 or tubular welded metal sheet used to form the stents is manufactured by using a laser cutting tool to prepare the slots 18 and 8 in either a sheet of metal or plastic. The laser tool cuts out each of the slots 18 and 8 from a preprogrammed pattern. Other methods of cutting can be employed such as photochemical etching, water jet cutting and similar mechanisms where energy in different forms are applied for cutting of the flat metal sheet or a tubular welded metal sheet. The metal can be stainless steel, titanium, nickel, a thermal alloy such as NITINOL or other metal compatible with a patient's vascular tissue.

When the device as seen in Figure 1 is assembled into the multiple stent 10 as seen in Figures 2 and 3, the body 12 is formed into a roll and the edges 13 and 15 are fused together by any suitable means such as plasma energy fusing, LASER fusing, ultrasound fusing. This feature is in common with all of the embodiments of the present invention. The body can be formed in a roll and fused together before forming the slots over a solid tubular structure.

The multiple stent 10 or individual stent as shown in Figures 19 and 20 may be coated, in a first inventive process, in the manner described with reference to Figures 21-27. As seen in Figures 21 and 22, the stent 10 may be placed over a solid plastic or metal generally cylindrical mandrel 115 so that the inner surface 111 of the stent 10 snugly engages the outer surface 117 of

the mandrel 115 in the manner seen in Figures 25 and 27. With the stent 10 so mounted as best seen in Figure 22, the stent 10 and mandrel 115 may be placed within the recess 125 of a second, larger mandrel 120 having a large generally cylindrical outer surface 121. As seen in Figures 23 and 25, in particular, the recess 125 is generally cylindrical in nature and is eccentrically placed with respect to the body of the second mandrel 120 so that the recess 125 intersects with the periphery of the mandrel 20 at an elongated slot 123 extending throughout the longitudinal length of the second mandrel 120. Figure 24 shows the stent 10, the first inner mandrel 115 and the second mandrel 120 as assembled together. In the configuration shown in Figure 24, the entire assembly is dipped in a bath of coating material so that, as best seen in Figure 25, a coating 130 is formed about the periphery of the mandrel 120 and attaches to the stent 10 at the area designated by the reference numeral 131 in Figure 25 that corresponds to the location of the elongated slot 123 within the mandrel 120. As should be understood, the slot 123 permits covering material to enter the recess 125 in the mandrel 120 in an elongated path along the longitudinal length of the stent 10 at one location therealong to affix the coating 130 thereto. Otherwise, the unexpanded stent 10 is uncoated. Figure 30 shows a side view of the assembly of the coated stent 10 and the mandrels 115 and 120 as seen in Figure 24.

Figure 26 shows removal of the stent 10, the mandrel 115 and the coating 130 from the mandrel 120. If necessary, a lubricant may be employed for this purpose. The cross-sectional view of

Figure 27 shows the stent 10 with the coating 130 spaced therefrom except at the area designated by the reference numeral 131 where the coating 130 is firmly attached to the stent 10. Subsequently, the mandrel 115 is removed from the interior of the stent 10.

With reference to Figure 33, the coated stent 10 is used by inserting a balloon catheter 135 snugly within the unexpanded stent 10 and by loosely wrapping the coating 130 about the stent 10 so that the configuration is small enough to be easily inserted within a blood vessel as shown in Figure 34. As should now be understood, when the balloon catheter 35 is expanded in a manner well known to those skilled in the art, the stent 10 expands so that the outer surface 112 thereof peripherally engages the inner surface 133 of the coating 130 so that, in the expanded state, the stent 10 is fully covered with a coating that has complete integrity.

Figure 28 shows a plurality of flat pieces 1a, 1b and 1c interconnected together by resilient flexible connectors 40, each of which consists of a series of rows of generally "X"-shaped members fixed together as shown. As should be understood, the device shown in Figure 10 may be assembled into a triple stent by forming the entire assembly into a roll as understood with reference to Figures 1 and 2.

Figure 29 shows an assembly 50 that consists of regions 151, 153 and 159, each one of which corresponds to the flat piece of material 1 as seen in Figure 1. The members 151 and 153 are interconnected together by the connecting portion 157 while the members 153 and 159 are interconnected together by the connecting

portion 155. The device 150 illustrated in Figure 29 may be assembled into a triple stent, again, in the manner that should be understood from Figures 1 and 2. The connecting portions 157 and 155 allow longitudinal expansion of the length of the device 150 in the directions of the double headed arrow 161.

In the embodiments illustrated in Figures 10 and 11, the free edges 2′, 3′ and 2", 3", respectively, may be interconnected in the manner described with reference to Figure 20.

The flat piece of material 1, 1a, 1b or 1c is manufactured by using a laser cutting tool to prepare the slots in rows 6 and 7 of Figure 19 in either a sheet of metal or plastic. The laser tool cuts out each

of the slots for rows 6 and 7 from a preprogrammed pattern. The metal can be stainless steel, titanium, nickel, a thermal alloy such as NITNOL or other metal compatible with a patient's vascular tissue. The coating 30 is a biocompatible material such as polyurethane, polyethylene, polytetrafluroethylene, silicone, block co-polymers of polyurethane, polyethylene and silicone, a biodegradable polymer such as polylactic acid, polyglycollic acid, and or hydroxy butyrate or valerate co-polymer. Biocompatible material will not interfere with blood or blood vessel interior wall tissue. The polymers can include anticoagulant agents, growth factor and like agents for reducing the reaction of blood to foreign surfaces.

Plastics employed to make the flat piece of material 1, 1a, 1b or 1c can be polyethylene, polyurethane, polytetrafluroethylene,

silicone or copolymer of polyurethane and polyethylene compatible with the vascular tissue of a patient.

With reference to Figure 30, as explained hereinabove, the mandrel 120 has been employed to create a single coated stent 10. Figure 21 shows the use of the mandrel 120 to provide coatings 130a and 130b on two stents 10a and 10b. Alternatively, Figure 32 shows the use of the mandrel 120 to create three coatings 130a, 130b and 130c on respective stents 10a, 10b and 10c.

With reference, now, to Figures 35-38, a further process in accordance with the teachings of the present invention is depicted. In Figures 35 and 36, a stent 170 is shown that is of the type that is known as "self-expandable". Such a stent is programmed to self-expand at a particular temperature either by using the shape memory properties of the metal or by using the inherent flexibility and elasticity thereof. The stent 170 as depicted in Figures 35 and 36 is shown prior to the programming step. A mandrel 71 is inserted within the stent 170. Thereafter, with reference to Figure 37, one or more stents 170 are dipped in a container 173 containing a liquid coating with the mandrels 171 being supported on a support 175 in a manner that should be well understood. For example, the container 173 may contain a polymeric coating material. After sufficient time has elapsed with the stent 170 immersed within the bath in the container 173, the stents 70 are removed from the bath, still attached to their respective mandrels 171, and are subsequently immersed within a rinse bath to remove excess coating. Thereafter, with reference to Figure 38, the stents 170, still

attached to their respective mandrels 171 which are attached to the support 175, are placed within an oven 180 having an internal chamber 181 with a heating element 183 connectable to a source of power (not shown). The stents 170 are heated to a desired temperature for a desired period of time and excess solvents are removed during the heating process. The suitably coated stent 170 with the coating 172 thereon is seen in Figure 39.

With reference to Figures 40, 41 and 42, a preferred method of use of the stent 170 is seen. After the process depicted in Figures 35-38, the stent 170 is suitably programmed. For example, the stent 170 may be dipped into a cold bath at a desired temperature and retained under cool temperature for a period of time so that when it is exposed to body temperature it expands to a desired degree of expansion. In the case of stents that are of the type that expand due to the inherent elasticity thereof, the stent is physically compressed. In either case, in the compressed state, the stent is covered with a non-expansible sheath 85 that prevents expansion until expansion is desired.

Figure 40 shows the stent 170 encased within the sheath 185 and inserted using an appropriate mechanism 187 into a blood vessel at an appropriate location. With reference to Figure 41, the sheath 185 is then removed and, with reference to Figure 42, the stent 170 expands either due to its inherent elasticity or due to exposure to body temperature within the blood vessel and performs its function. As should be understood from the above description, the process illustrated in Figures 35-38 also may be employed in

coating the stent employing the mandrels as illustrated in Figures 21-27. In either case, for solvent-based polymeric coatings where the solvent can be eluted out of the material by a chemical or mechanical treatment procedure, the polymeric coating solution contains a solvent. The solvent may suitably be removed by heat (as explained with reference to Figure 38), by vacuum or through the use of a non-solvent. If desired, several dips into the tank 173 may be carried out to provide the desired final wall thickness of the coating.

Concerning the process described with reference to Figures 21-27, the portion 131 of the coating where it attaches about the stent 10 may be reinforced with a line of sutures.

With further reference to the process illustrated in Figures 3-27, where thin wall coatings are employed that are not solvent based and which can be extruded into a very thin conduit, the conduit may be slipped onto the eccentric mandrel 20 and may be attached to the stent by welding, adhesive or by a line of sutures. Conduits that may be employed in this regard include those made of polyurethane, expanded polytetraflorol ethylene (TEFLON), extruded TEFLON, polyester which may be knit or woven, velour or non-velour, extruded, PET, PE, hydrogels that can impart a desirable elastic nature to the walls of the coating. These choices are merely given by way of example.

Additionally, biological materials such as collagen, gelatin and the like may be suitably employed. In the case of "self-expanding" stents such as the stent 70, the coating material may be

solvent based, extruded or biological and may be assembled to the mandrel and attached to the "self-expanding" stent either by a continuous suture or intermittently placed sutures along one axis of the stent or by an adhesive or any other mechanical, thermal or chemical treatment that ensures attachment. The stent and the coating material are together programmed to expand at body temperature. For example, the stent and coating may be dipped in a cold bath with the coating attached to reduce them both to a much smaller size which may then be inserted into a sheath which may be removed within the body to allow expansion to the expanded size when the coating was originally applied.

Hereinabove, the use of a hydrogel material for the coating was suggested. Such a material is especially effective since it is very pliable and elastic and has an extremely slippery surface allowing easy removal from the overlying sheath.

With reference to Figure 4, a second embodiment of multiple interconnected stents is designated by the reference numeral 20 and includes a plurality of pieces 11 forming stents as explained above. Adjacent stents are interconnected by virtue of U-shaped members 27, 29 that are fused together at various points and interconnected to each stent as shown in Figure 4. These interconnectors 27, 29 are flexible and resilient.

Figure 5 shows a third embodiment of the present invention generally designated by the reference numeral 30 and including a plurality of rectangular pieces 11 formed in a single sheet 31 integrally incorporating interconnectors 33, each of which consists

of a plurality of rows 35, 37 of slots 36, 38 with each row of slots 36, 38 having spaces 39 between adjacent slots that are staggered in adjacent rows. The slots 36, 38 are orthogonal to the slots 8 and 18 of the rectangular piece 11.

Figure 6 shows a fourth embodiment of the present invention generally designated by the reference numeral 40 and including a plurality of pieces 11 interconnected by double bars 41, 43. These double bars 41, 43 are similar to the single bars 25 in the first embodiment illustrated in Figures 1-3. However, as seen in Figure 6, different sets of double bars 41, 43 are vertically staggered with respect to one another.

Figure 7 shows a fifth embodiment of the present invention generally designated by the reference numeral 50 and including a plurality of pieces 11 interconnected by interconnectors 51 consisting of a plurality of vertically spaced connectors 53, each resembling the letter "H" with additional horizontal legs 55 connecting the "H"-shaped connector 53 to each piece 11.

Figure 8 shows a sixth embodiment of the present invention generally designated by the reference numeral 60 and including a plurality of pieces 11 with adjacent pieces 11 being interconnected by a multiplicity of vertically spaced bars 61. This embodiment is similar to the embodiment of Figures 1-3 except that a multiplicity of bars 61 are employed instead of the single bars 25 of the Figures 1-3 embodiment.

Figure 9 shows a seventh embodiment of the present invention generally designated by the reference numeral 70 and including a

plurality of pieces 11 interconnected together by a plurality of vertically spaced interconnectors 71, each one of which is flexible and resilient and resembles the letter "W". At the lateral sides of each connector 71, a short lateral section 73 is provided to connect the connector 71 to each adjacent piece 11.

Figure 10 shows a side view, partially in cross-section, of the multiple stent 10 of the embodiment of Figures 1-3 as contained within a blood vessel 1. An appliance 80 is shown inserted through the pieces 11 to convey the entire multiple stent 10 to a desired location within the blood vessel 1. Figure 11 shows the device 80 which is better seen with reference to Figures 12, 13, 16, 17 and 18. As seen, the device 80 includes a plurality of expander blocks 81 mounted on a spreader mechanism 83 including legs 85, 87 pivoted together at a pivot 89 and interconnected to an actuator mechanism 91 at the pivots 93. A wire 95 extends through the tube 97 and connects to the actuator 91 whereby when the wire 95 is pulled in the direction of the arrow 99, the actuator 91 moves to the right in the view of Figure 18 to cause separation of the blocks 81 to the position shown in Figures 13 and 18 whereby the stent 10 is expanded to engage the walls 3 of the blood vessel 1.

Other views of the device 80 are also seen in Figures 16 and 17 with Figures 14 and 15 showing an alternative insertion device 100 having eight blocks 101 rather than the four blocks 81 of the device 80. The insertion device 100 spreads the forces of enlargement of the stents 10 more uniformly around the circumference thereof.

The stents employed in this invention are about 1.5-2.5 mm in length and the interconnections about 0.30 mm to 0.60 mm in length. The total length of an interconnected stent is 5 mm to 60 mm in length to form segments of the rigid slotted stents and flexible interconnections.

As such, an invention has been disclosed in terms of preferred embodiments thereof which fulfill each and every one of the objects of the invention as set forth hereinabove and provide new and useful interconnected stents, a polymer coated microporous stent and method of coating of great novelty and utility.

Of course, various changes, modifications and alterations in the teachings of the present invention may be contemplated by those skilled in the art without departing from the intended spirit and scope thereof.

As such, it is intended that the present invention only be limited by the terms of the appended claims.

CLAIMS

1. A multiple stent comprising:

a) first and second stents, each stent formed from a generally rectangular body formed into a tube, said body having top and bottom edges fused together to form said tube, said body having a plurality of parallel rows of longitudinal slots, each row having a plurality of longitudinal slots separated from one another by spaces, spaces in adjacent rows being laterally staggered with respect to one another;

b) said stents being interconnected together by flexible interconnection means.

2. The multiple stent of Claim 1, wherein said interconnection means comprises a bar.

3. The multiple stent of Claim 2, wherein said bar comprises a plurality of bars.

4. The multiple stent of Claim 1, wherein said interconnection means comprises a U-shaped member on said first stent attached to a U-shaped member on said second stent.

5. The multiple stent of Claim 4, wherein each of said U-shaped members comprises a plurality of U-shaped members.

6. The multiple stent of Claim 1, wherein said stents are formed in a single rectangular body.

7. The multiple stent of Claim 6, wherein said interconnection means comprises a plurality of interconnection slots in said single rectangular body orthogonal to said slots of said stents.

8. The multiple stent of Claim 1, wherein said interconnection means is "H" shaped.

9. The multiple stent of Claim 8, including a plurality of "H" shaped interconnection means.

10. The multiple stent of Claim 1, wherein said interconnection means is "W" shaped.

11. The multiple stent according to claim 1 wherein a coating surrounds an outer surface of said tube, said coating being attached to an outer surface of said tube at one peripheral location and being spaced from said outer surface at other peripheral locations when said stent is unexpanded;

12. The stent of claim 11, wherein said coating is made of a polymeric material.

13. The stent of claim 12, wherein said polymeric material is microporous.

14. The stent of claim 11, wherein said coating is made of a biologic material taken from the group consisting of collagen and gelatin.

15. A preprogrammable self-expandable stent, comprising:

a) a tubular body having first and second ends and a wall extending between said ends, said wall having a plurality of parallel rows of spaced longitudinal slots, adjacent slots being separated by solid portions, adjacent rows of slots having solid portions laterally staggered with respect to one another;

b) a coating formed on substantially an entirety of an outer peripheral surface of said stent prior to programming of said

stent;

c) whereby said stent may be subsequently programmed to expand to an expanded configuration responsive to exposure to temperature of a human body.

16. The stent of Claim 15, wherein said coating is made of a polymeric material.

17. The stent of Claim 10, wherein said polymeric material is microporous.

18. The stent of Claim 16, wherein said coating is made of a biologic material taken from the group consisting of collagen and gelatin.

19. The stent of Claim 15, further including a further stent laterally adjacent thereto, said stent and further stent being interconnected with a flexible connection.

20. A method of coating a stent including the steps of:

a) providing a tubular stent having a multi-slotted peripheral wall;

b) inserting a first tubular mandrel into said stent;

c) inserting said stent and first tubular mandrel into a recess formed in a second mandrel, said second mandrel having an outer periphery intersecting with said recess at a slot;

d) dipping said stent with said first and second mandrels into a coating bath to coat said outer periphery of said second mandrel with a coating;

e) causing said coating to enter said slot and adhere to said stent peripheral wall at a location adjacent said slot;

f) removing said stent and mandrels from said bath; and

g) removing said stent from said mandrels, said stent having said coating affixed thereto at said location.

21. The method of Claim 20, further including the step of forming said first and second mandrels of generally cylindrical shapes.

22. The method of Claim 21, further including the step of locating said recess eccentrically with respect to an axis of elongation of said second mandrel.

23. The method of Claim 20, further including the step of applying continuous sutures or intermittently placed sutures at said location.

24. The method of Claim 20, further including the step of providing said recess with an elongated linear configuration.

25. A method of coating a preprogrammable self-expandable stent including the steps of:

a) providing a preprogrammable self-expandable tubular stent having a multi-slotted peripheral wall prior to programming;

b) inserting a mandrel through said stent;

c) coating said stent to form a coated stent;

d) programming said coated stent to expand at a desired temperature.

26. The method of Claim 25, further including the step, after said programming step, of covering said coated stent with a removable sheath.

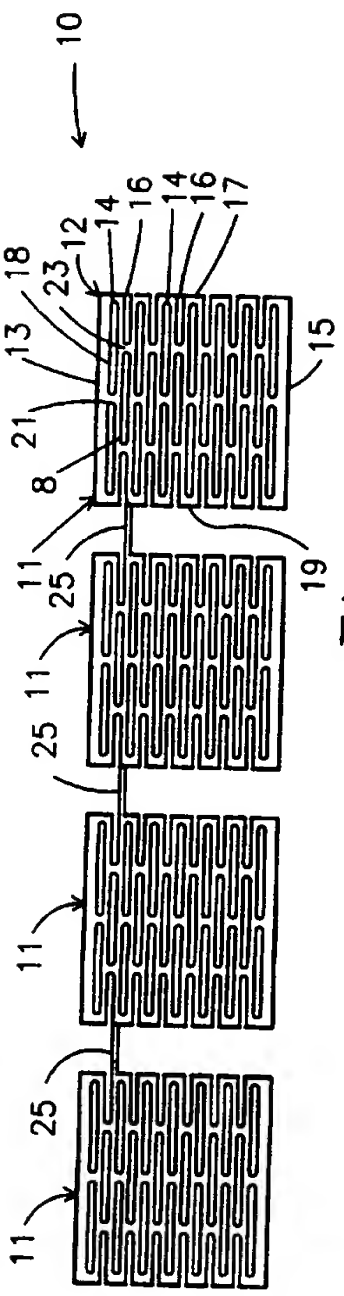


Fig. 1

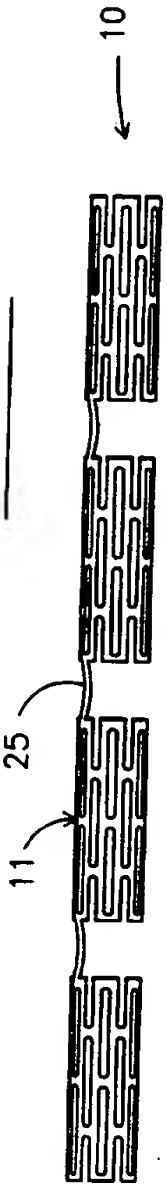


Fig. 2

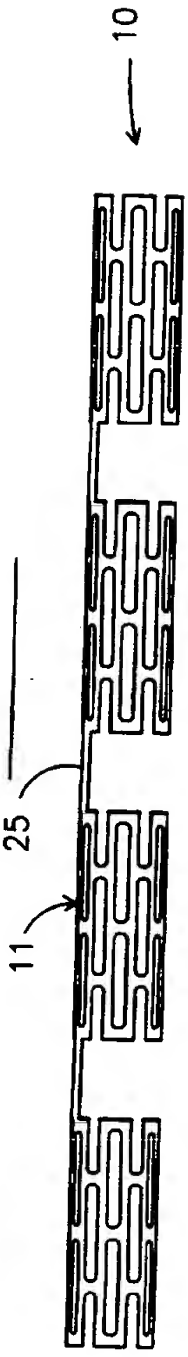


Fig. 3

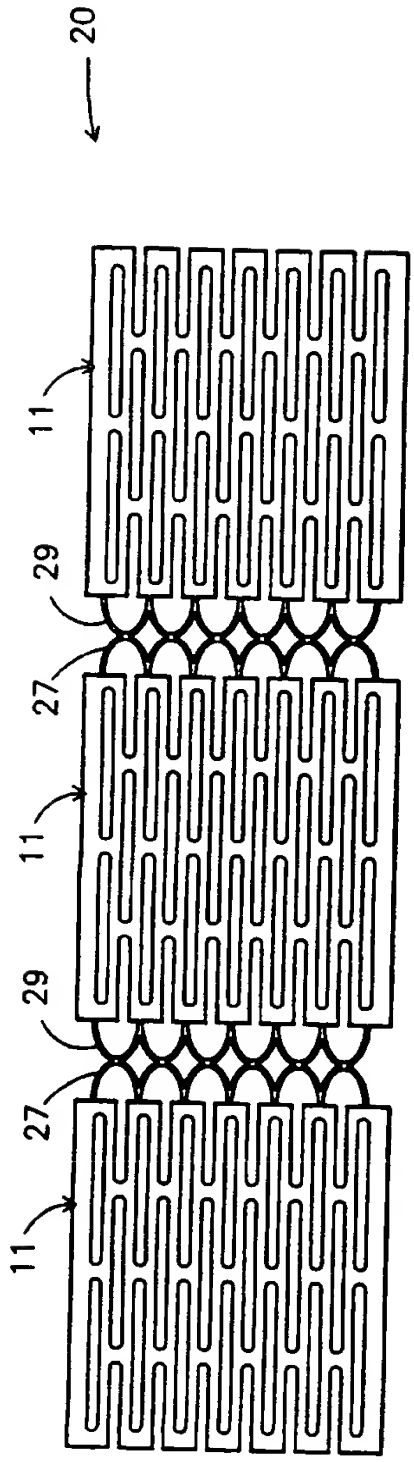


Fig. 4

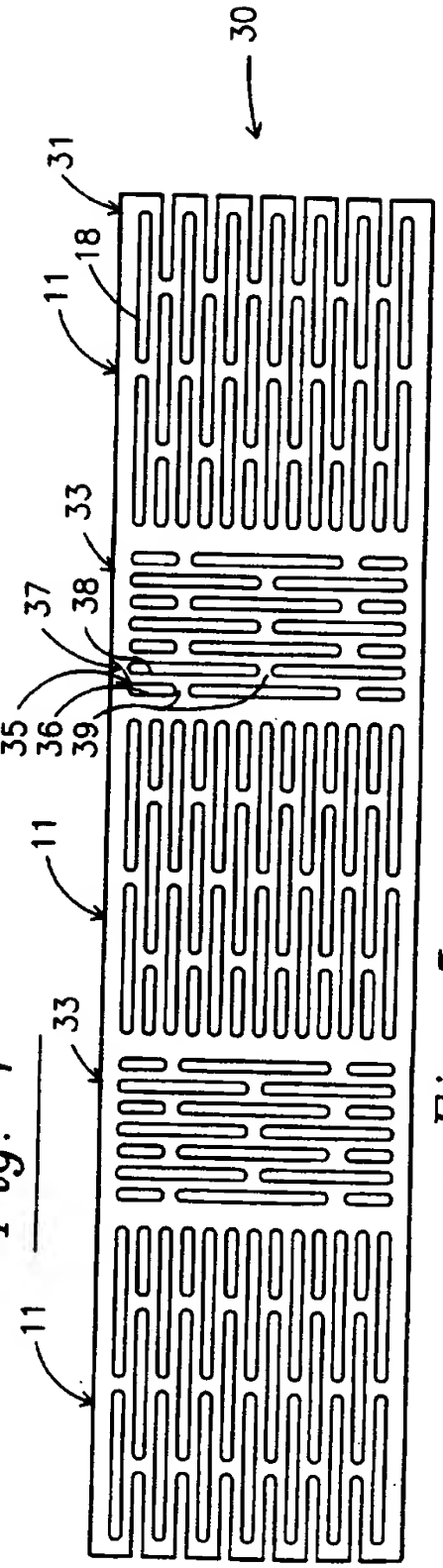


Fig. 5

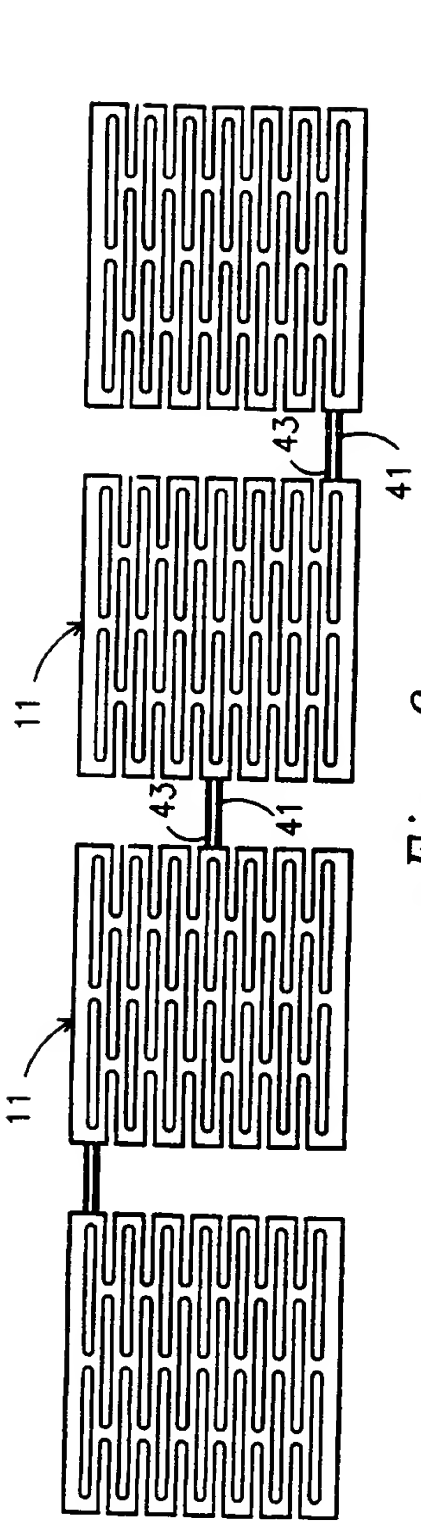


Fig. 6

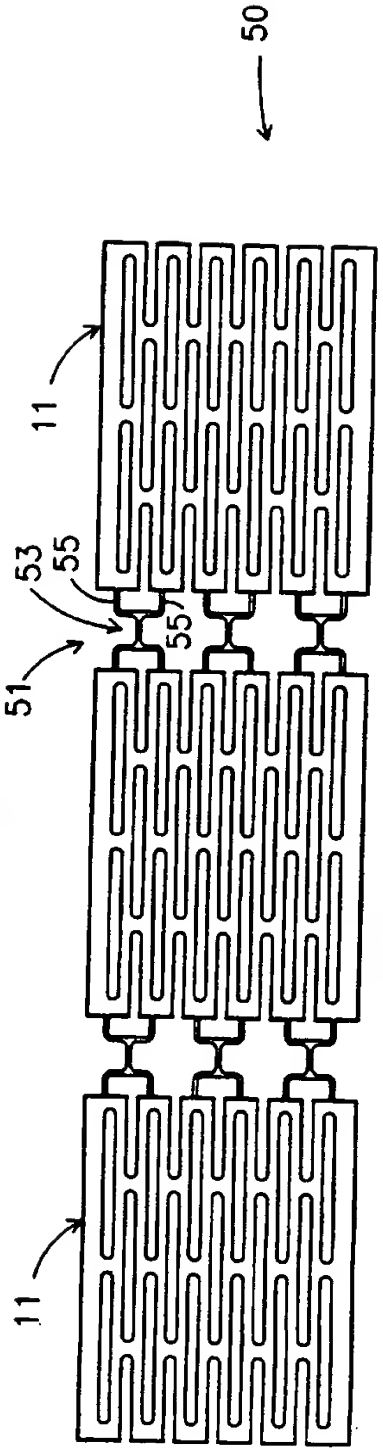


Fig. 7

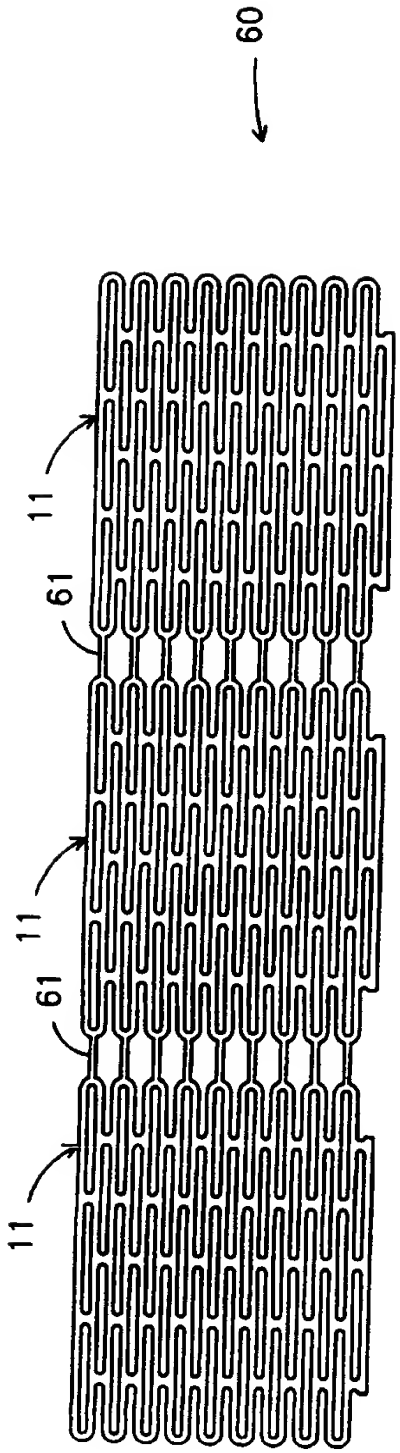


Fig. 8

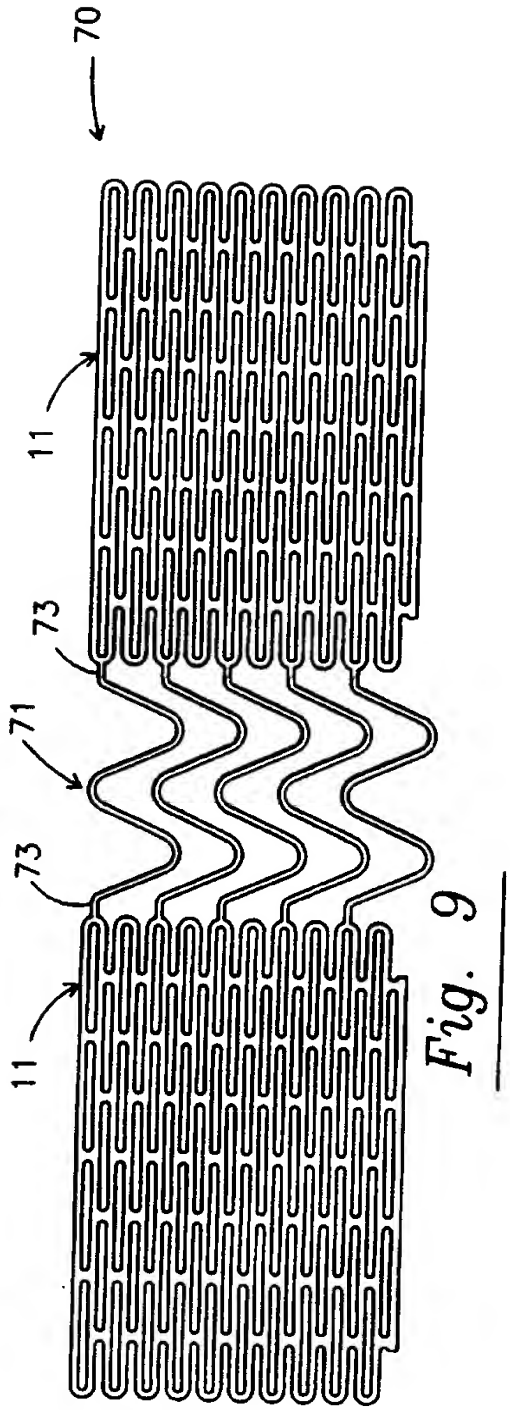


Fig. 9

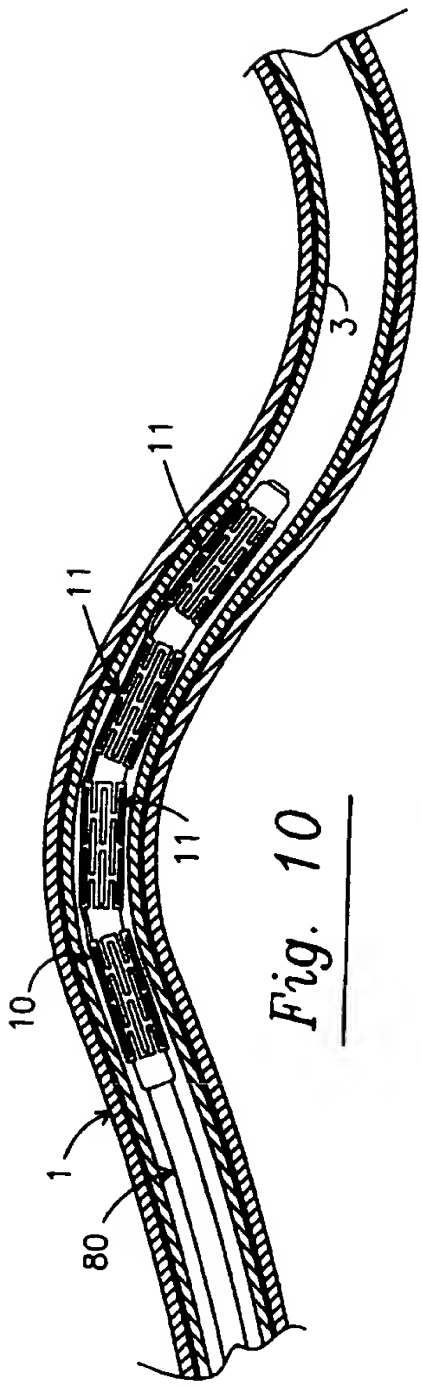


Fig. 10

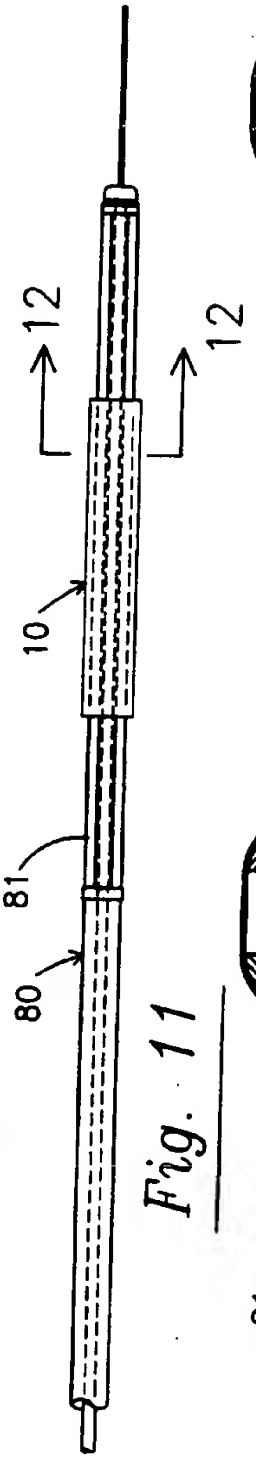


Fig. 11

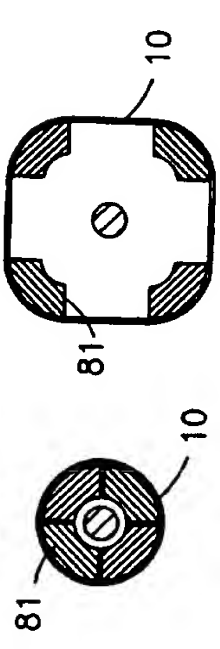


Fig. 13

Fig. 14

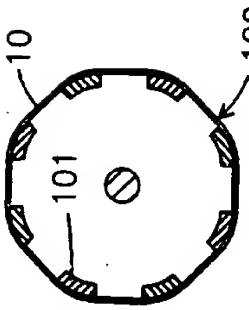
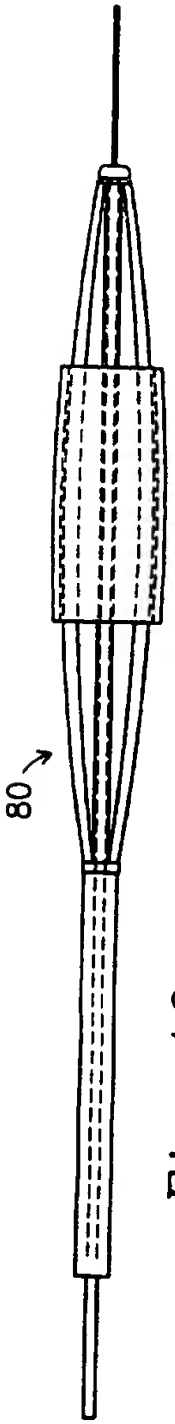


Fig. 15

Fig. 12



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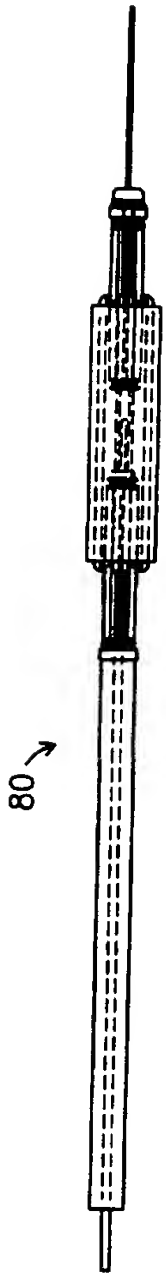

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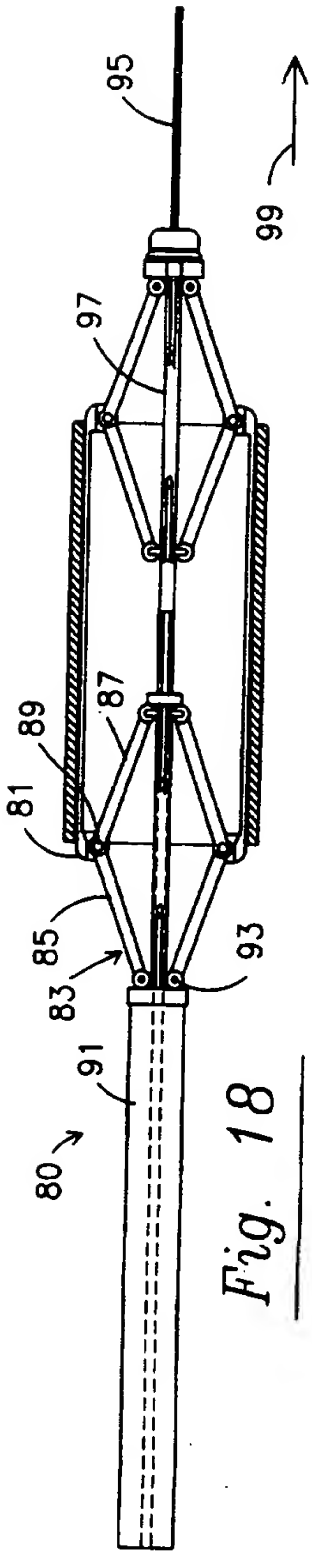

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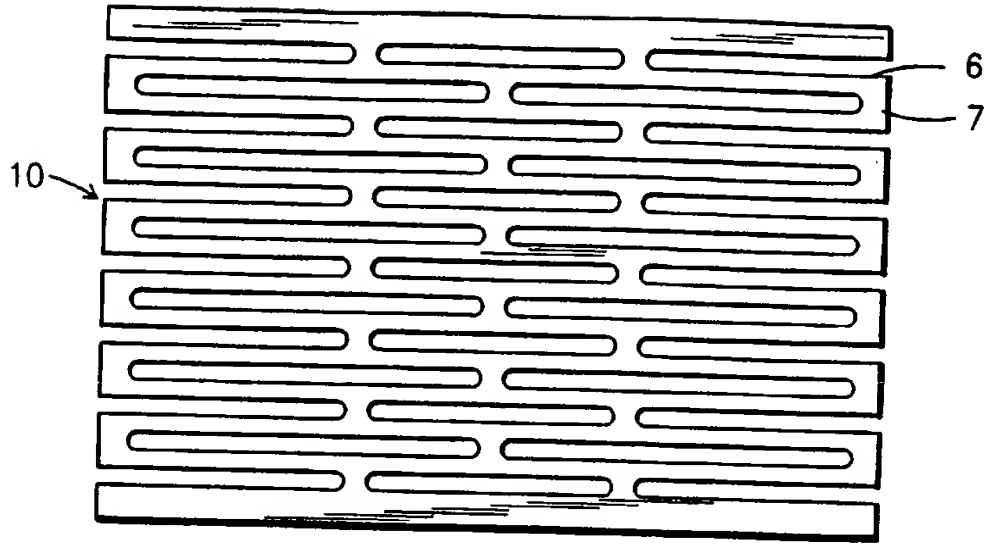


Fig. 19

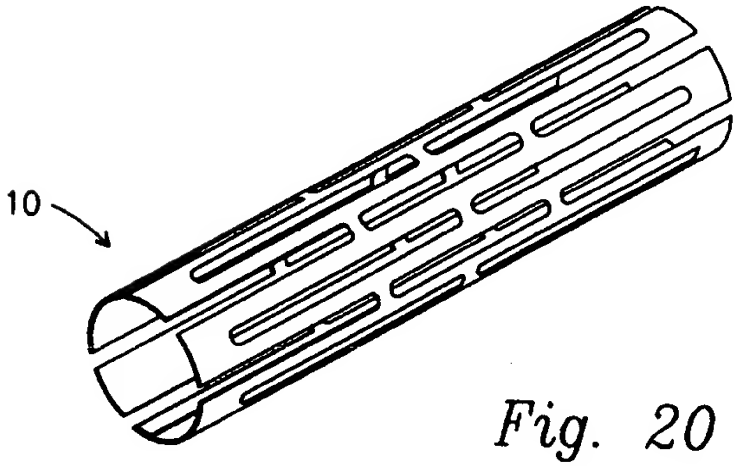
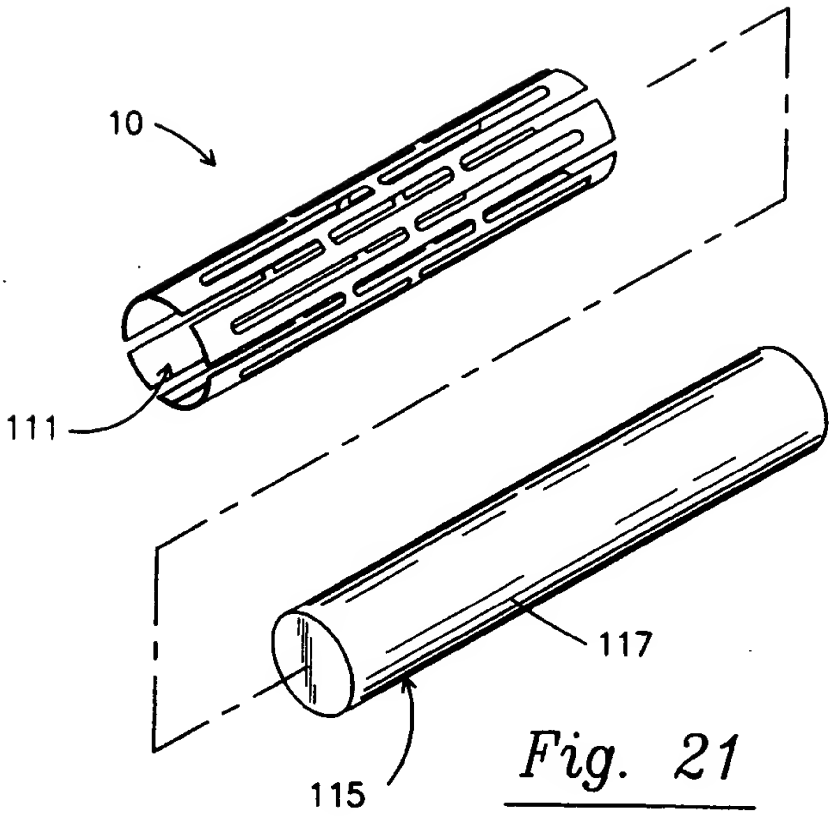


Fig. 20



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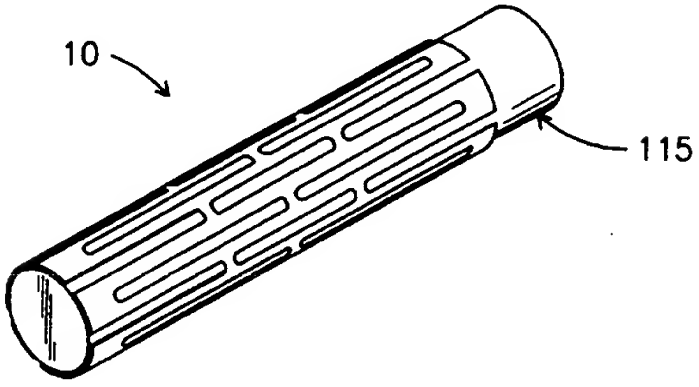


Fig. 22

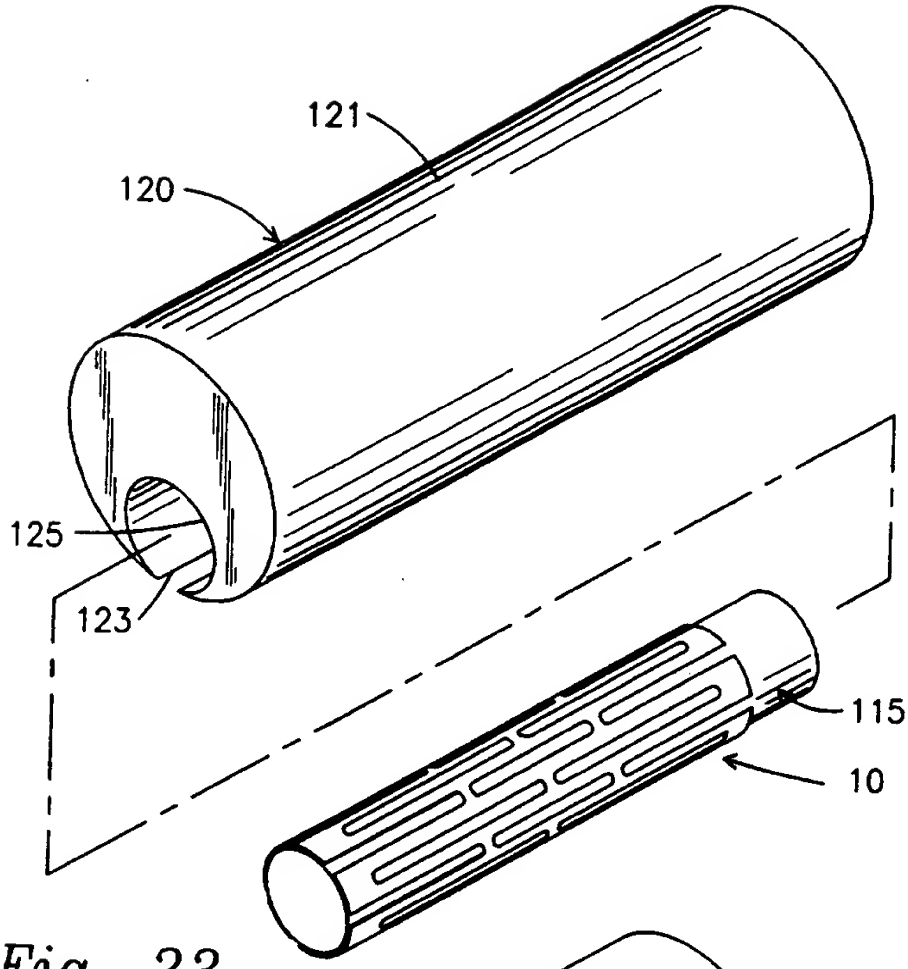
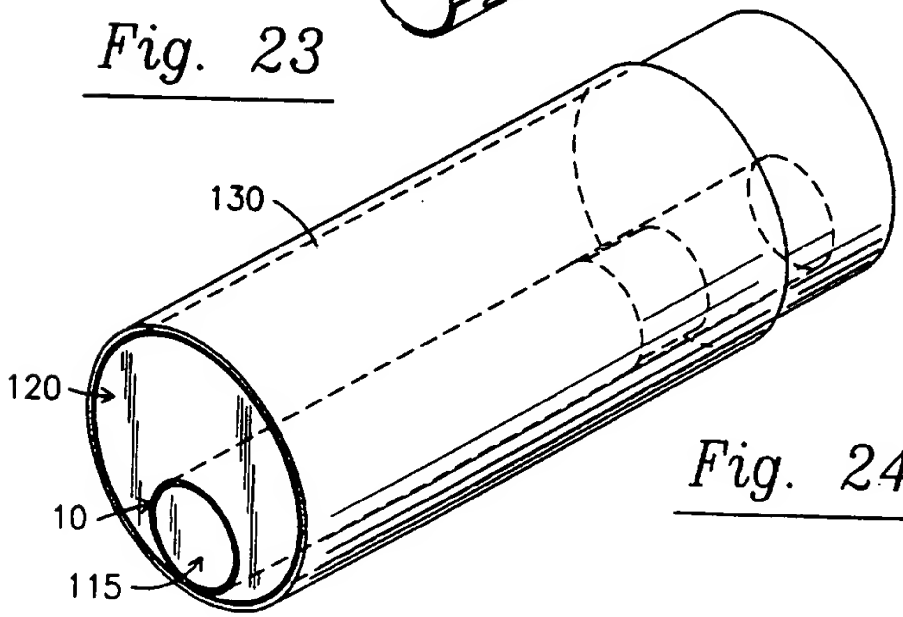


Fig. 23



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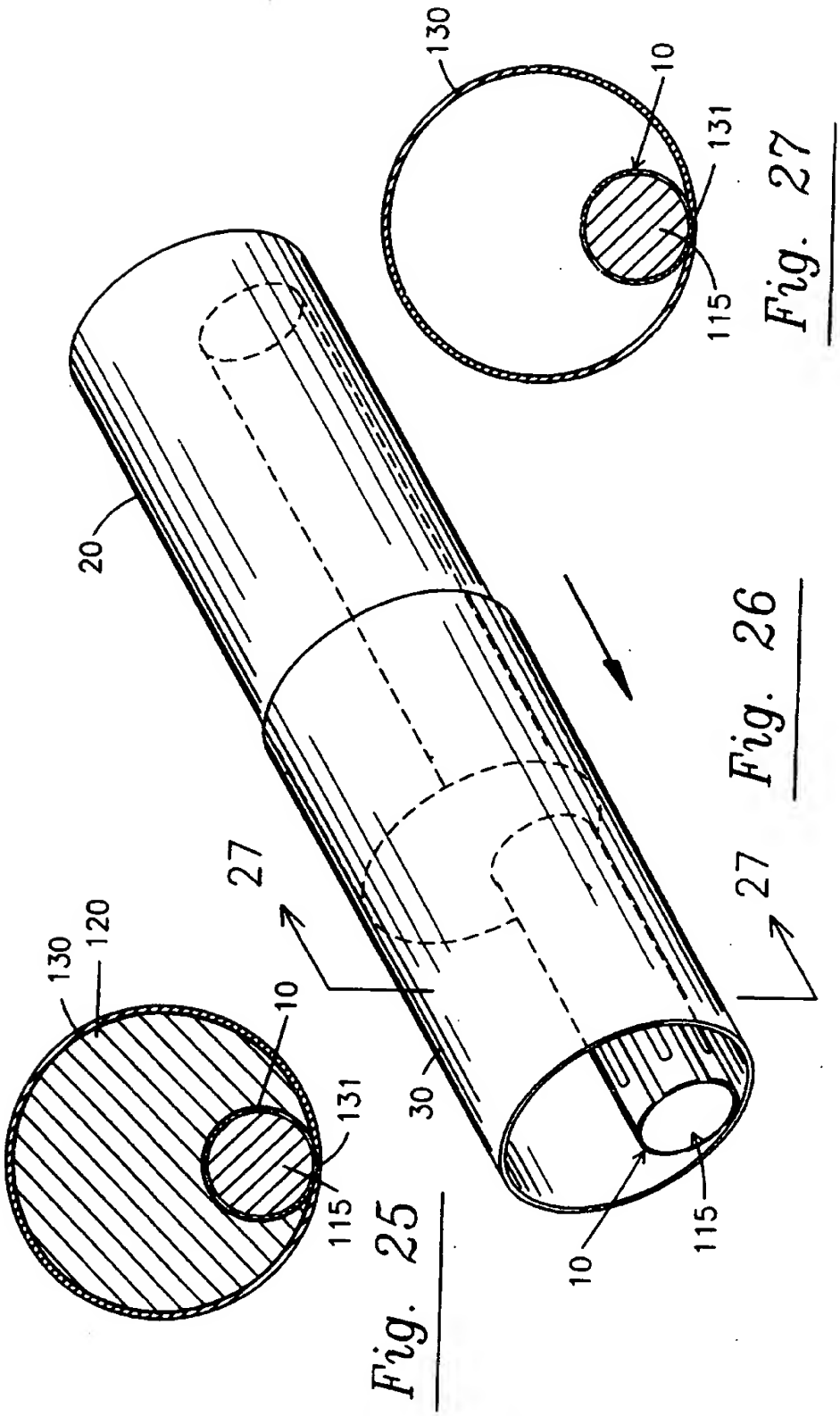


Fig. 25

Fig. 26

Fig. 27

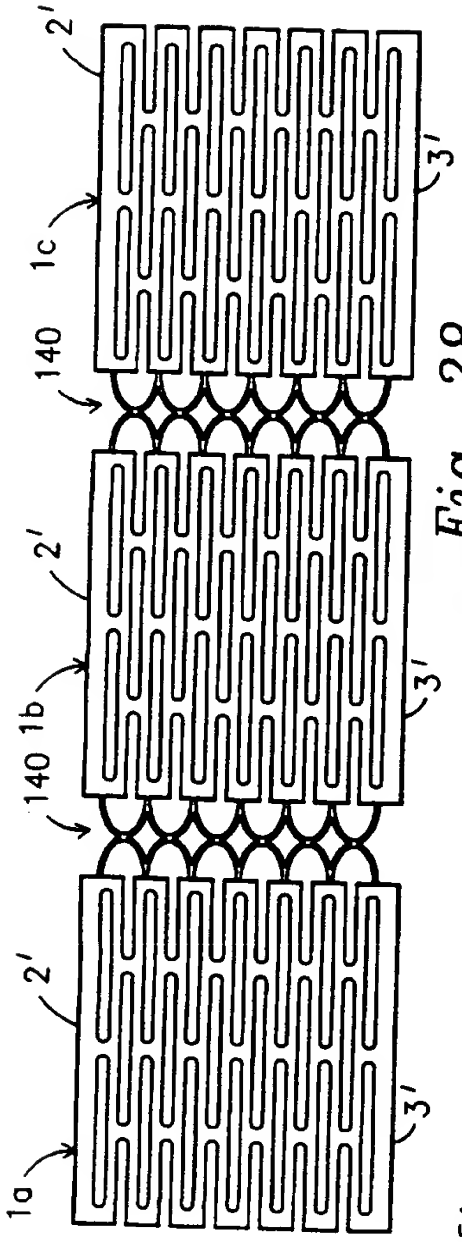


Fig. 28

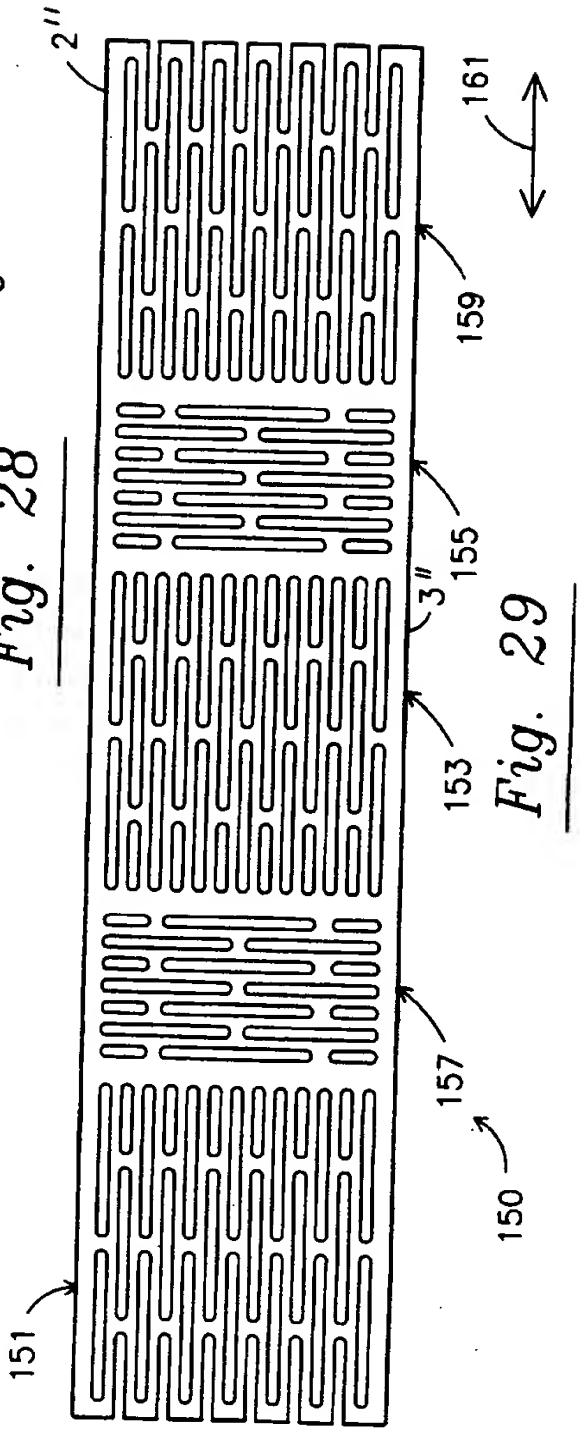


Fig. 29

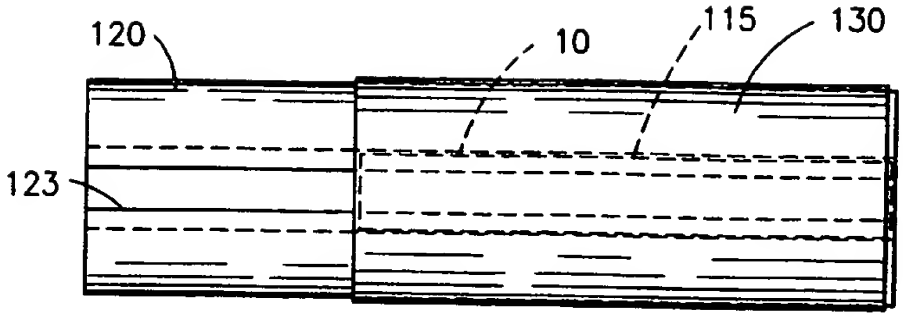


Fig. 30

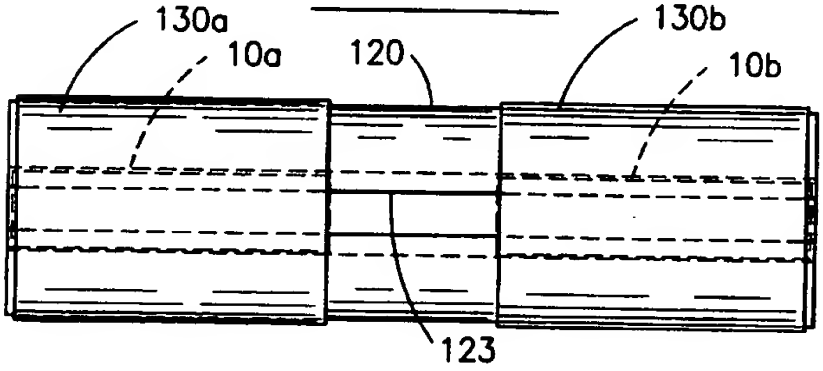


Fig. 31

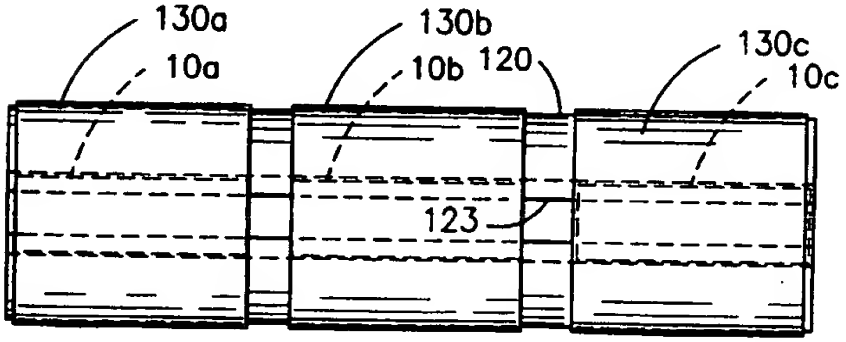


Fig. 32

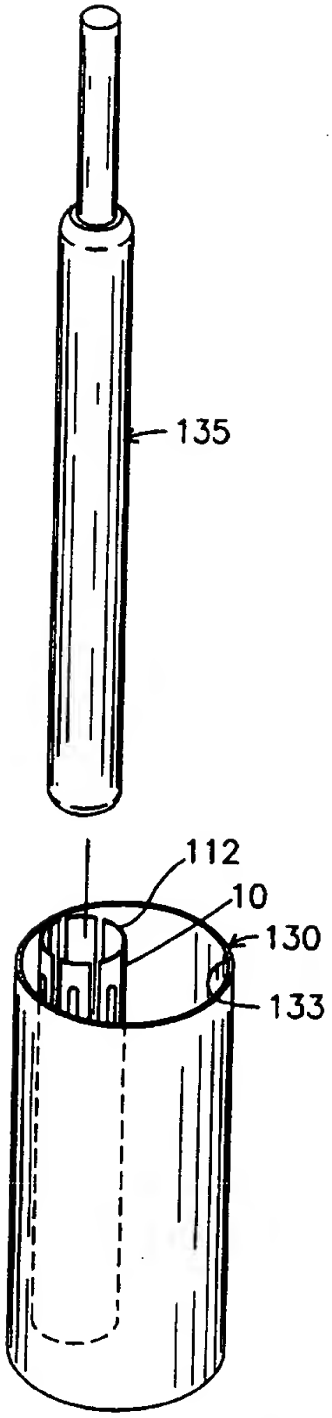


Fig. 33

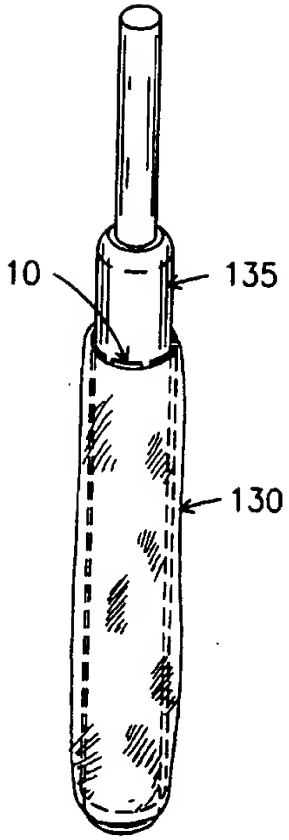
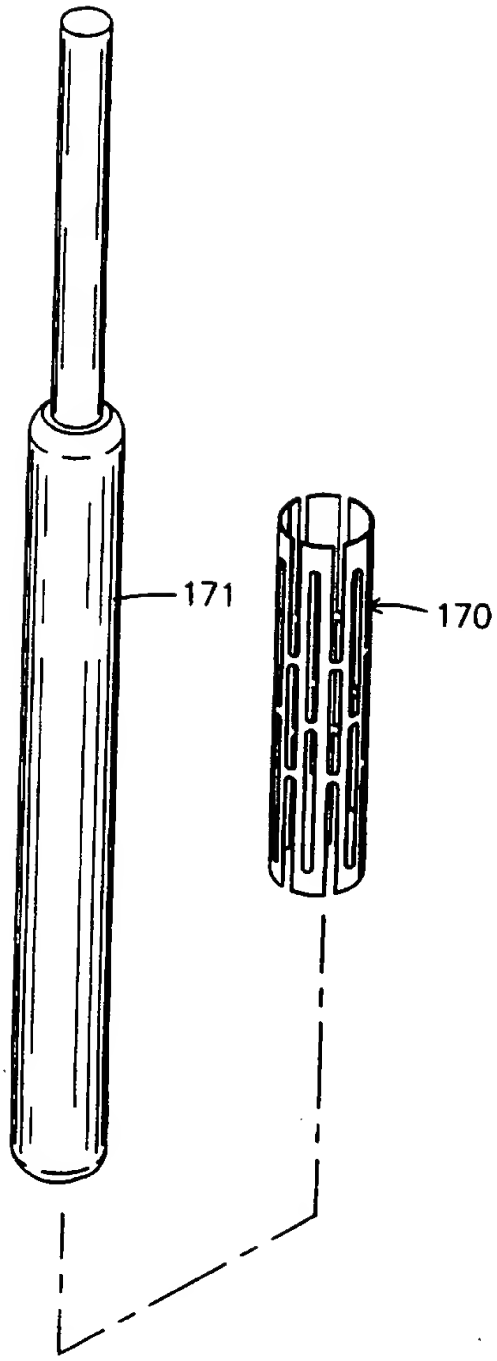


Fig. 34



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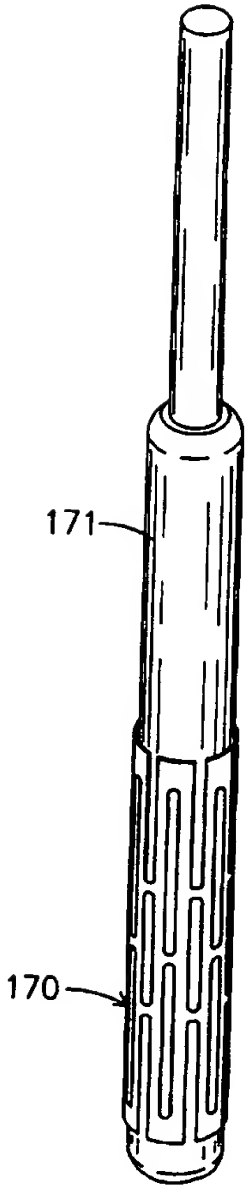


Fig. 36

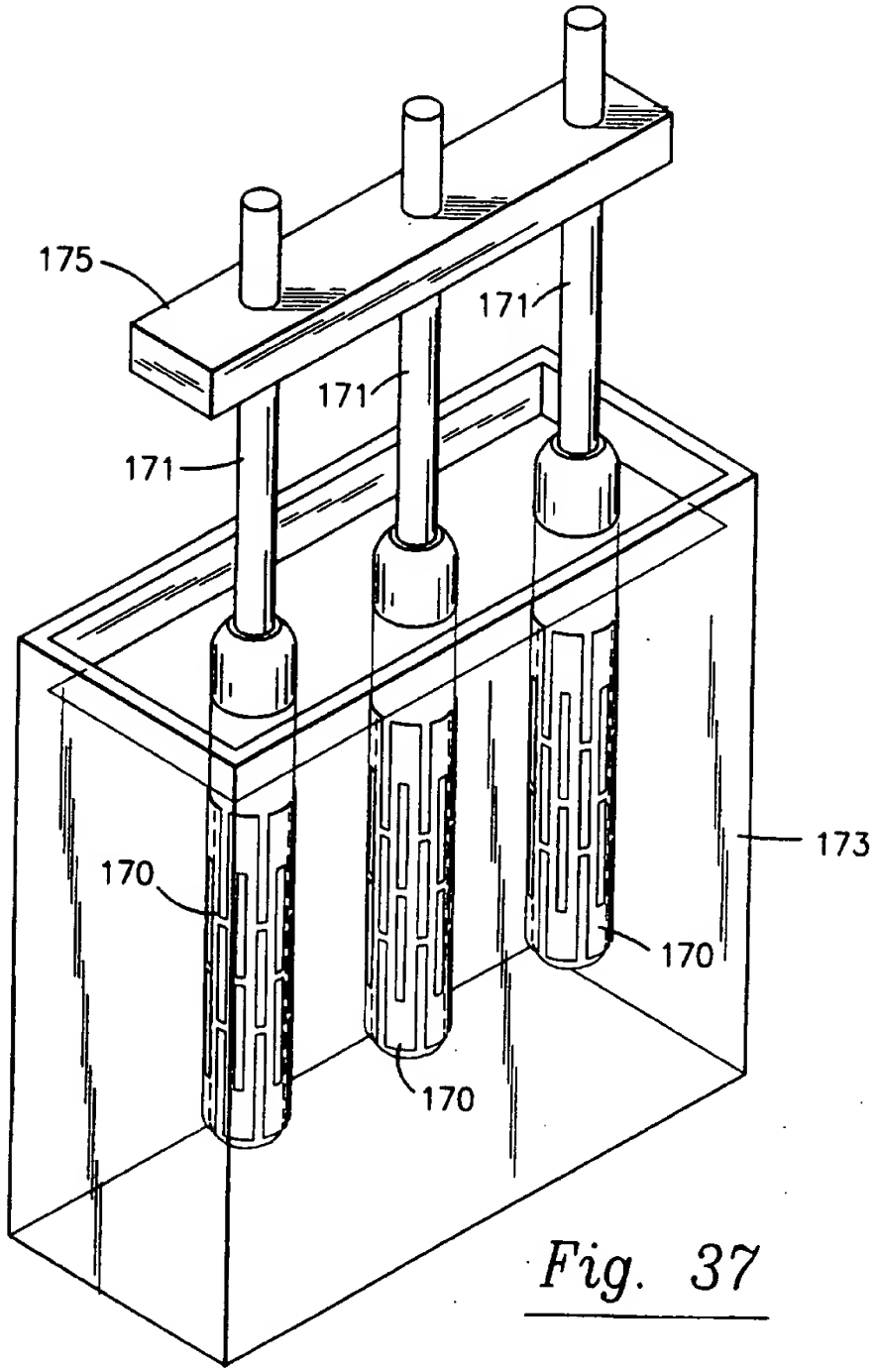


Fig. 37

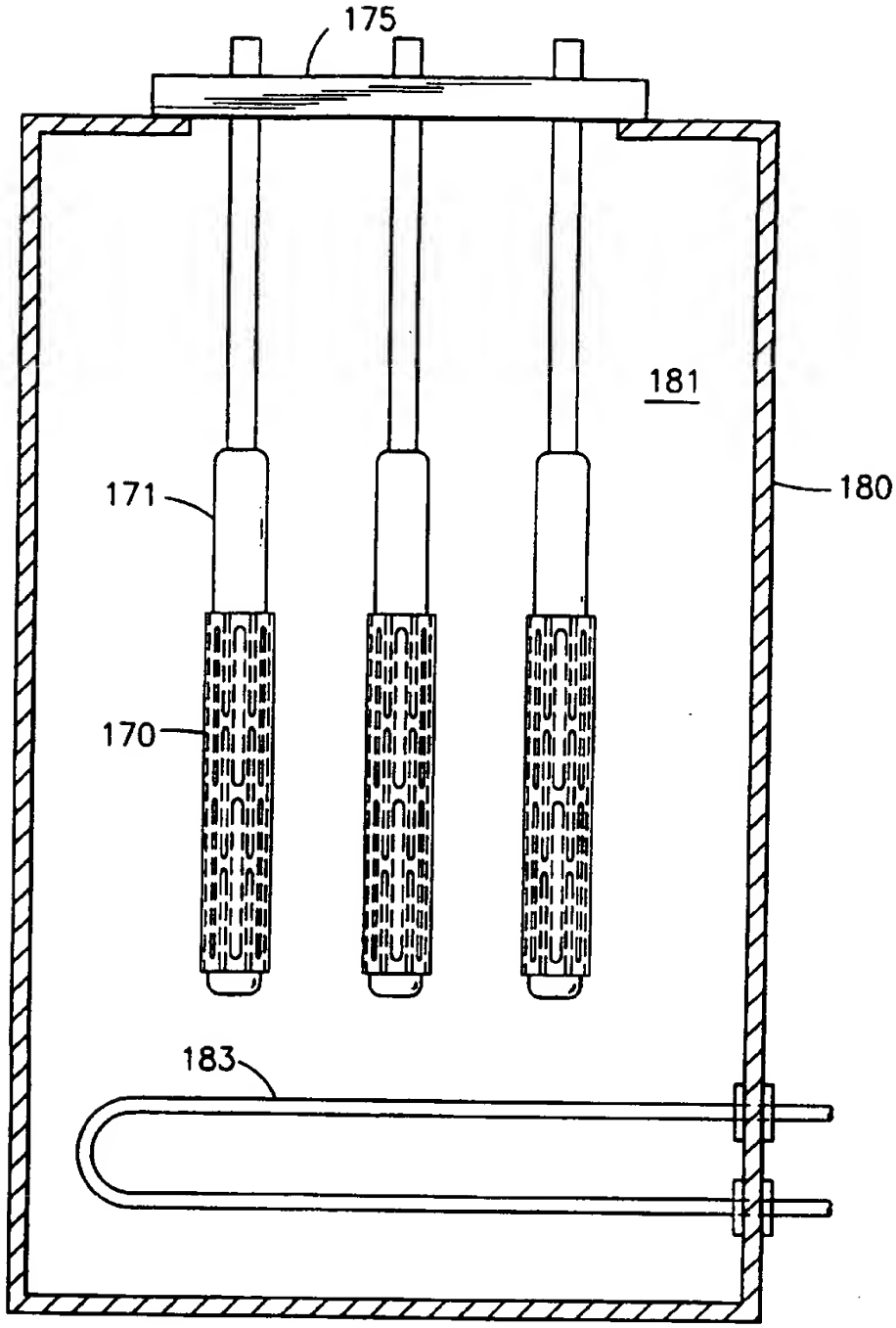


Fig. 38

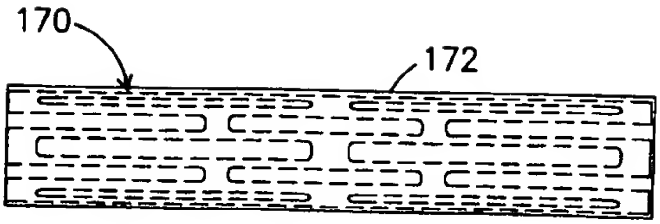
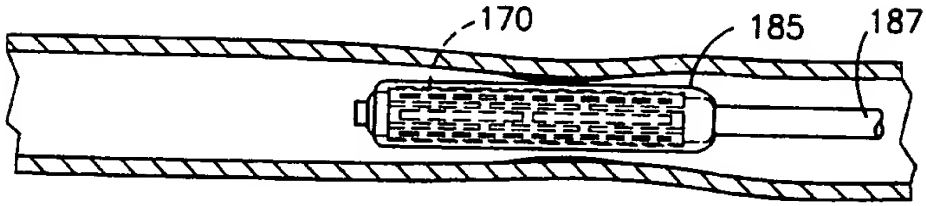


Fig. 39



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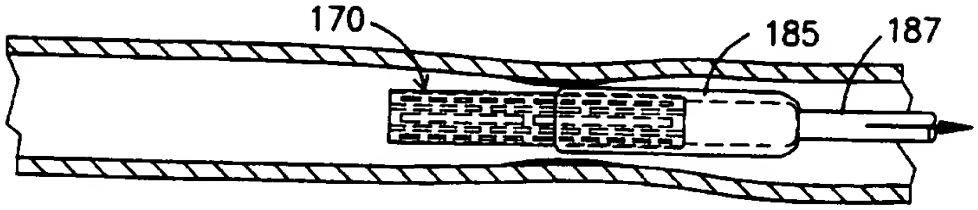

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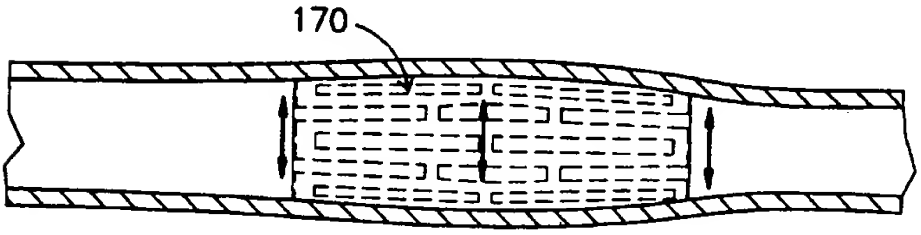

Fig. 42

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/06098

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL : 606/194,192; 623/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/194,192; 623/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,102,417 A (Palmaz) 07 April 1992, Fig. 10.	1-9
X	US 5,449,373 A (Pinchasik et al.) 12 September 1995, Figs. 3A-3C.	1-3 and 10
X	US 3,657,744 A (Ersek) 25 April 1972, column 2.	1-3,11-19, 25, and 26
A	US 5,421,955 A (Lau et al.), 06 June 1995.	1-26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" documents which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 JUNE 1997	07 JUL 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Patrick Rasche Telephone No. (703) 308-3523

Form PCT/ISA/210 (second sheet)(July 1992)*